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**BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES**

Application Number: 10/505,305  
Filing Date: October 27, 2004  
Appellant(s): BRETON ET AL.

\_\_\_\_\_  
Robert M. Barrett  
For Appellant

**EXAMINER'S ANSWER**

This is in response to the appeal brief filed 3/3/09 appealing from the Office action mailed 12/24/08.

**(2) Related Appeals and Interferences**

The following are the related appeals, interferences, and judicial proceedings known to the examiner which may be related to, directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal:

Application Serial No. 10/504,906.

**(3) Status of Claims**

The statement of the status of claims contained in the brief is correct.

**(4) Status of Amendments After Final**

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

**(5) Summary of Claimed Subject Matter**

The summary of claimed subject matter contained in the brief is correct.

**(6) Grounds of Rejection to be Reviewed on Appeal**

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

**(7) Claims Appendix**

The copy of the appealed claims contained in the Appendix to the brief is incorrect in that claims 11-24 are currently withdrawn from consideration and are not cancelled as stated by appellant.

**(8) Evidence Relied Upon**

7,037,708	RUNGE	5-2006
5,603,930	BRASSART	2-1997
4,806,368	REDDY	2-1989
EP 1020123	CAVALIERE VESELY	7-2000
WO 00/70972	BERGGREN	11-2000

**(9) Grounds of Rejection**

The following ground(s) of rejection are applicable to the appealed claims:

**(a) The rejection of claims 1-10 and 25-30 under 35 U.S.C. § 103.**

Claims 1-10 and 25-30 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Cavaliere Vesely *et al.* (EP 1020123) taken with Runge *et al.* (U.S. Patent No. 7,037,708), Berggren *et al.* (WO/0079072) and Brassart *et al.* U.S. Patent No. 5,603,930) and further taken with Reddy (U.S. Patent No. 4,806,368).

The claims are directed to an orally administrable composition comprising a photoprotecting effective amount of at least one probiotic lactic acid bacterium, at least one carotenoid in an amount of  $10^{-12}$  to 20% by weight, an ingestible carrier and yeast extract.

Cavaliere Vesely *et al.* disclose an orally administrable composition such as a food or drink composition comprising a photoprotecting effective amount of at least one probiotic lactic acid bacterium such as *Bifidobacterium longum* and *Lactobacillus acidophilus*, at least one carotenoid in the amount required, B vitamins and an ingestible carrier. See, e.g., Examples 1-3, in particular Example 3.

Runge *et al.* disclose an orally administrable composition such as a food composition comprising a photoprotecting effective amount of at least one probiotic lactic acid bacterium and at least one carotenoid in the required amount and an ingestible carrier. See, e.g., Example S2. The dried mixture comprises *Lactobacillus plantarum* and at least  $\beta$ -carotene in powder form, wherein the ingestible carrier is maltodextrin. This material is orally administrable and constitutes a food composition.

Berggren *et al.* disclose an orally administrable composition such as a food or drink composition comprising a photoprotecting effective amount of at least one probiotic lactic acid bacterium and at least one carotenoid in the required amount and an ingestible carrier. See, e.g., Examples 1-3, wherein sports drinks are provided, which are clearly drinkable. The composition comprises *Lactobacillus plantarum* and  $\beta$ -carotene. In Example 3, tablets are provided.

The references differ from the claimed invention in that the specific strains of claim 4 are not disclosed and in the provision of milk products, milk based fermented products that are drinkable, such as yogurt.

However, Brassart *et al.* adequately demonstrates that at least strain *Lactobacillus johnsonii* CNCM I-1225 was old and well known in the art as a probiotic suitable for oral administration at the time the claimed invention was made. In addition the reference demonstrates that the composition is provided as a yogurt, a milk-based fermented product. See, e.g., col. 3, lines 55-60. Brassart *et al.* also teach the use of freeze-dried cultures in a carrier such as milk or yogurt. See, e.g., col. 1, lines 46-54, which are drinkable compositions.

With regard to the pharmaceutical carrier, it is noted that the product of Berggren is provided at least in tablet form (see, e.g., Example 3). In addition, the yogurt composition containing strain *Lactobacillus johnsonii* CNCM I-1225 disclosed in Brassart constitutes a pharmaceutical carrier that is a drinkable composition comprising the strain of interest.

Regarding the presence of yeast extract, it is noted that Reddy adequately demonstrates that compositions of *Lactobacillus* and *Bifidobacterium* containing yeast extract are old and well known in the art. See, e.g., Col. 3, Table. The reference discloses the benefits of the yeast extracts components to the viability of the bacteria, for example as a source of B vitamins in the food composition. Therefore, the replacement of B vitamins as taught by Cavaliere Vesely with yeast extract would have been an obvious expedient for one of ordinary skill in the art.

The concentrations discussed in the references appear to be substantially the same as claimed. However, even if they are not, the adjustment of concentrations for optimization purposes identified as result-effective variables cited in the references would have been prima facie obvious to a person having ordinary skill in the art, since such adjustment is at the essence of biotechnical engineering.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to modify the compositions of Cavaliere Vesely *et al.*, Runge *et al.* and Berggren *et al.* by providing a composition comprising a photoprotective amount of the probiotic strain *Lactobacillus johnsonii* CNCM I-1225 and other related probiotic strains as suggested by the teachings of Brassart *et al.* and including yeast extract as taught by Reddy *et al.* for the expected benefit of providing a healthful composition comprising a probiotic strain in a

photoprotecting amount known to have favorable effects against disease and providing carotenoids such as  $\beta$ -carotene as well as yeast extract, materials known to have at least antioxidant effects and containing vitamin B, respectively.

Thus, the claimed invention as a whole was clearly *prima facie* obvious, especially in the absence of evidence to the contrary.

#### **(10) Response to Argument**

Appellant contends that "the presently claimed oral composition includes an admixture of specific constituents that surprisingly and unexpectedly elicit an enhanced effect or response with respect to the photoprotection of the skin" citing the specification, page 14, lines 6- 11. However, there is nothing specific about the compositions as claimed directed broadly to include at least one unidentified probiotic lactic acid bacterium, amounts of carotenoids as low as 0.000000000001% and yeast extract in amounts that read on traces thereof.

Appellants alleges that the skilled artisan would not arrive at the claimed invention using the cited references in the absence of hindsight because the cited references are entirely directed to compositions utilizing different nutritional ingredients for different intended purposes. However, the compositions disclosed by the references are all orally administrable and include at least one probiotic lactic acid bacterium, with Cavaliere Vesely containing carotenoids and vitamin B and Runge and Berggren specifically containing carotenoids in at least 0.000000000001% and Reddy specifically containing at least one probiotic lactic acid bacterium and yeast extract.

In response to appellant's argument that there is no suggestion to combine the references (Brief, page 15, last paragraph, et seq.) the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. In re Fine, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988; In re Jones, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992).

In this case, the *Cavaliere Vesely et al.*, *Runge et al.*, *Berggren et al.* are all directed to orally administrable compositions comprising lactic acid probiotics and carotenoid and at least *Cavaliere Vesely et al* and *Berggren et al.* contain vitamin B, and *Reddy* specifically contains at least one probiotic lactic acid bacterium and yeast extract, even though the references do not teach that the composition can be used for photoprotection of the skin.

However, the intended use of the composition does not distinguish the composition since such undisclosed use is inherent in the cited compositions. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art compositions. In the instant case, the intended use does not create a structural difference, thus, the intended use is not limiting. "The claiming of a new use . . . which is inherently present in the prior art does not necessarily make the claim patentable." *In re Best*, 195 USPQ 430, 433 (CCPA 1977). When appellant claims a "composition in terms of function . . . and the composition of the prior art is the same as that of the claim but the function is not explicitly disclosed by the reference, the Examiner may make a rejection under both 35 U.S.C. 102 and 103, expressed as a 102/103 rejection" (MPEP 2112). In this regard, it is noteworthy that the claims are directed to a composition comprising "10<sup>-12</sup>% to 20% by weight of an unidentified carotenoid.. There is nothing on the record to indicate to what extent a composition comprising carotenoids at the lower end of the range recited will have the required effect.

As noted previously the addition of yeast extract to probiotic lactic acid compositions is well known in the art for its viability enhancement and provision of vitamin B.

It is enough to provide merely a reason to combine references in an obviousness rejection. In the instant case the provision of a healthy probiotic composition suitable for ingestion by the combination of probiotic, carotenoids and yeast extract comprises such a reason. Additionally, the combining of known equivalents, in this case probiotic strains, for the same purpose of providing an orally administrable composition, carotenoids and vitamin B, for example, has long been held obvious, see *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069 (CCPA 1980).

Appellants argues that the Affidavit under 37 C.F.R. §1.132 demonstrates the deficiencies of the prior art with respect to the present claims, because it demonstrates the surprising and unexpected synergistic photoprotective effects resulting from ingestion of the

presently claimed composition comprising an admixture of a photoprotecting effective amount of at least one probiotic lactic acid bacterium, at least one carotenoid, and yeast extract. In the declaration, the declarant states at 4. that the invention is directed, in part, to an oral composition that includes an admixture of very specific constituents and alleges synergistic effects therefor. However, claim 1 is directed to

"An orally administrable composition for the photoprotection of the skin comprising a photoprotecting effective amount of at least one probiotic lactic acid bacterium, and at least one carotenoid wherein the at least one carotenoid is present in the composition in an amount from  $10^{-12}\%$  (0.000000000001%) to 20% by weight, included in an orally acceptable carrier, the composition further comprising a yeast extract".

There is nothing specific about the constituents of this composition. The invention as claimed in the independent claim is directed very broadly to any probiotic lactic acid bacterium and is directed to various species thereof in claim 3. Only in claim 4 are specific strains claim designated, of which at least one strain is known in the art as shown by Brassart but they are not required to be live. In addition, the invention as claimed encompasses unidentified carotenoids at a level of between  $10^{-12}\%$  to 20% by weight. The nature of the carotenoids and the amount of  $10^{-12}\%$  are not addressed in the declaration and cannot be considered to be "specific". Moreover the compositions comprises an unidentified amount of yeast extract from unidentified yeasts.

The declaration shows favorable results for a composition comprising "matrix + La1  $10^8$  live + UV and this is designated "composition according to the invention". In section 8. it is stated that

"Depending on the group being tested, the mice were fed a variety of formulas of food including a food with no additional supplements; a food with maltodextrin; a "matrix" food having beta-carotene, lycopene, inactivated yeast extract and excipients such as, for example, magnesium stearate, corn starch, and silicon dioxide; a food with carotenoids; and the "matrix" food that was also supplemented with a bacteria (La1). The formulas for the treatments are set forth in Table 1 of Exhibit B."

However, Table 1 of the Declaration does not disclose the actual components fed. Thus, there is no clear nexus or correlation between the invention as claimed and the results provided. There is no clear nexus or correlation between a composition comprising  $10^8$  live La1 of the declaration and the invention as claimed directed to any probiotic lactic acid bacterium in any



amount, the various species of claim 3 and even the specific strains of claim 4, which do not appear to include any amount of live "La1", which is not identified with any specificity in this record. It has been independently determined by the Examiner that "La1", is, in fact, *Lactobacillus johnsonii* CNCM I-1225.

In addition, the declaration does not specify the level of carotenoids between  $10^{-12}\%$  to 20% by weight in the composition or the amount of yeast extract. It is also noted that claim 5 specifically recites "semi-active" or deactivated" lactic acid bacteria as opposed to "live" as in the declaration.

Appellant further states that the "specific" combination of the probiotic lactic acid bacterium, the carotenoid, and the yeast extract that provides the surprising and unexpected "synergistic" photoprotective effects on the skin, citing Figure 2 of Exhibit B. Appellant argues that the increased amount of swelling of the right ear of the mice tested with respect to columns 2 and 3 indicated that the skin reacted readily to the presence of the allergen on the right ear. In other words, the skin reacted readily to the presence of the allergen on the right ear because the animal did not experience local immunosuppression due to exposure to UVR.

These data are not probative of unexpected results in the absence of specific identification of the ingredients and the amounts thereof in the "matrix" provided to the test subjects. Synergism is an unpredictable phenomenon which is highly dependent upon specific proportions and/or amounts of particular ingredients. Appellant does not set forth with sufficient particularity the combinations of specific ingredients that provided the touted results in the Declaration and the respective amounts used. In addition, no specific identification of the ingredients and the amounts thereof are provided in the claimed invention.

Appellant argues that the skilled artisan would understand that broadening out the La1 - *Lactobacillus johnsonii* to encompass other probiotics and broadening out lycopene to encompass other carotenoids serves as Appellants' prophetic examples (Brief, page 15, paragraph 2). However, these allegations are not persuasive of error in the rejection.

In short, the Declaration does not specifically and particularly distinguish over the art and is not probative of unexpected results since it is not commensurate in scope with the claims. The scope of the showing must be commensurate with the scope of claims to consider evidence probative of unexpected results, for example. In re Dill, 202 USPQ 805 (CCPA, 1979), In re

Lindner 173 USPQ 356 (CCPA 1972), In re Hyson, 172 USPQ 399 (CCPA 1972), In re Boesch, 205 USPQ 215, (CCPA 1980), In re Grasselli, 218 USPQ 769 (Fed. Cir. 1983), In re Clemens, 206 USPQ 289 (CCPA 1980). It should be clear that the probative value of the data is not commensurate in scope with the degree of protection sought by the claim.

In response to Appellant's allegations that there is absolutely no guidance in the cited reference for one of skill in the art to choose the active agents and amount of agents present in the instant claims to achieve the unexpectedly improved photoprotective effect on the skin as Appellants have done (Brief, page 16, paragraph 2), it is noted that specific agents or amounts of specific agents are not recited in the claim designated invention that provide for "unexpectedly improved photoprotective effect on the skin" (Brief, page 15, last paragraph). Not even in the Declaration are the ingredients alleged to have "unexpectedly improved photoprotective effect on the skin" properly identified as to the nature and amounts thereof.

Appellant's arguments and Declaration have failed to rebut the strong *prima facie* case of obviousness made out over the references. Therefore the rejection is deemed proper and it is adhered to.

**(11) Related Proceeding(s) Appendix**

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Irene Marx/  
Primary Examiner  
Art Unit 1651

Conferees:

/Michael G. Wityshyn/  
Supervisory Patent Examiner, Art Unit 1651

/Cecilia Tsang/  
Supervisory Patent Examiner, Art Unit 1654